



Organic Trade Association
Comment on the "Clarification on the definition of Synthetic, etc."

August 15, 2005

Submitted by:

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on behalf of OTA and its 605(b) Task Force

**Clarification of the definition of Synthetic as it is applied to Substances Petitioned for
Addition or Prohibition to the National List(s)**

Voted on by the Materials and Handling Committee 6/23/05

Introduction: This document is a draft for guidance purposes with the goal of clarifying the definition of synthetic as it pertains to determination for substances petitioned for addition or prohibition to the National List(s).

Background:

The NOSB uses the definition of synthetic as:

A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from a naturally occurring plant, animal or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes. (OFPA 2103 (21); 7 CFR 205.2).

Any substance other than those naturally occurring in a plant, animal or mineral is considered synthetic if it is formulated or manufactured by a chemical process.

Recommendation:

1) Extraction¹ shall be understood to mean:

Substances removed from naturally occurring plants, animals, or mineral sources can be extracted in any manner and with any substance, material, physical process (i.e. centrifugation, heating, chemical solvents, bases and acids), [or allowed processing method as defined by OFPA 2103\(21\) and the NOP rule \(205.270\) for organic handling operations](#), as long as the extraction process does not chemically change the substance that is being extracted. As long as a chemical reaction does not occur, the substances that are removed from a naturally occurring plant, animal or mineral source are non-synthetic, provided any synthetic substance used in the extraction process do not remain in the final product above insignificant levels and do not have any

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technical or functional effect. Any synthetic substance used in the extraction process that remains in the final extract above insignificant levels and any synthetic substance that has a technical or functional effect must be on the National List.

1 Extraction (NOSB, 1995; Austin, Texas); The concentration, separation and removal of a substance from a plant, animal microbiological or mineral source. Materials used in plant crop and animal production may be extracted in any way that does not result in synthetic reaction as defined by 2103(21). The products of any other methods of extraction shall be considered on a case by case basis and reviewed for compatibility under OFPA Sec. 2119 (m) (1-7).

Justification for inserting or allowed processing method as defined by OFPA 2103(21) and the NOP rule (205.270) for organic handling operations. Handlers may use extraction methods such as heat, enzymes, or water for processing agricultural products which results in a chemical change. These chemical changes are recommended by the NOSB to be allowed under OFPA 2103(21) and the NOP rule (205.270).

2) Formulation or manufacturing shall be understood to mean:

Once a substance is extracted, if it then undergoes a chemical reaction as it is processed, formulated or manufactured to produce agricultural or handling inputs, it then would be considered a synthetic and would have to be petitioned for inclusion on the National List.

Formulation or manufacturing as defined in this section is not intended to address the processing of an agricultural product* by a handling operation** or food (see definition below). This definition applies only to the individual inputs used in crop and livestock operations, and to the nonagricultural inputs used in handling operations. Additionally, if an extracted substance is formulated with other substances, those substances if synthetic would have to be petitioned for inclusion on the National List.

The definition of synthetic as defined in the regulation is clarified in this document as it applies to adding substances to the National List (205. 601-606). Processing of an agricultural product by a handling operation* or food may involve synthetic and non-synthetic substances on the list and these substances along with the agricultural component(s) may undergo chemical changes as they are processed. These chemical changes are allowed under OFPA 2103(21) and the NOP rule (205.270). Below is the section of the rule that allows for various methods in the processing of an agricultural product by a handling operation or food and it is included in this document to provide the distinction between formulation or manufacturing described above as it pertains to substances considered for addition to the National List (205. 601-606) and processing as allowed in the regulation.

Justification for adding “an agricultural product by a handling operation”.

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Food is not defined in OFPA nor in the NOP regulations. Instead, the Act clearly defines a Handler and Handling operation as any person engaged in the business of handling agricultural products. For clarification we recommend adding these to the document.

Definitions:

Food Drug & Cosmetic Act, Section 201(f) - The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

21 CFR 1.328(2): Food has the meaning given in section 201(f) of the act. Examples of food include, but are not limited to fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or as components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from the finished container and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals; bakery goods; snack foods; candy; and canned foods.

Food: any substance taken into and assimilated by a plant or animal to keep it alive and enable it to grow. from Webster's New World Dictionary of the American Language.

***Agricultural product.** Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption.

****Handling operation:** Any operation or portion of an operation (except final retailers of agricultural products that do not process agricultural products) that receives or otherwise acquires agricultural products and processes, packages, or stores such products)

3) Processing:

The following methods are allowed by OFPA 2103(21) and the NOP rule (205.270) for organic handling operations. Mechanical or biological methods including but not limited to "cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, distilling, slaughtering, cutting, fermenting, eviscerating, preserving, dehydration, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container."

Comment: OTA's Technical Taskforce asks the National Organic Program and the NOSB to further define "heating" and "or otherwise manufacturing".

We also recommend the following processing techniques be included in the interpretation of the definition of processing in order to provide further clarification: crystallization, evaporation (change from "dehydration" to "dehydration/evaporation") and pressing.

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4) Chemical reaction (chemical change) shall be understood to mean:

Comment: OTA's Technical Task force recommends the following change to point 4 to clarify the meaning of "chemical reaction (chemical change)".

4) Chemical reaction (chemical change) shall be understood to mean:

A chemical reaction has occurred when one or more atoms are removed or added to a substance due to a covalent bond change which results in the formation of an entirely new substance. The basic identity, physical properties, function in foods, physiological pathways for digestion/absorption, etc. of a substance can be changed when a covalent bond is either added or removed. Covalent bonds are difficult to break and cannot be broken by dissolving in water. In general, if an element is bonded to carbon, nitrogen or phosphorus, it has a covalent bond. The following is an example of a covalent bond change:

Monsanto process: carbon monoxide reacts with methanol under the influence of a rhodium complex catalyst at 180°C and pressures of 30 - 40 atm to form acetic acid. The following covalent bond changes occur in this process:



Changes in ionic bonds are not classified as a chemical reaction (chemical change) and do not result in a substance being classified as synthetic. Ionic bonds are much weaker bonds and are typically easily broken in water and reform as solutions are concentrated. The physical properties, function in foods, physiological pathways for digestion/absorption, etc. of substances with ionic bond changes are more related to the environment (food type, concentration, acidity, etc.) than the presence of the ionic bond. For example, sodium chloride is present as free ions in salt water (Na⁺ and Cl⁻). As sea water is concentrated, the positively charged sodium ions and negatively charged chloride ions form a weak bond which eventually results in the formation of salt crystals. When these salt crystals are re-dissolved in water, the sodium chloride again separates into free ions. The following example demonstrates that the form of the ionic bond (associated or disassociated) has little impact from a biological perspective. An individual who consumes a glass of tomato juice and a teaspoon of salt (ionically bonded sodium and chloride ions) experiences the same biological response as an individual who first dissolves the salt in tomato juice (breaking the ionic bonds) and then drinks the juice.

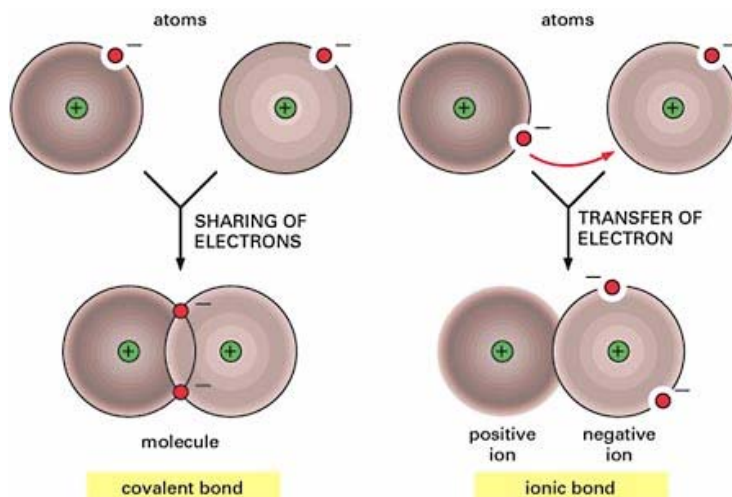
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Conclusion: In assessing chemical changes in substances of interest to the organic food industry, bonds are fairly easy to distinguish as covalent or ionic in nature. Identifying processing that results in covalent bond changes is fairly simple and also clearly delineates substances of most concern (completely new compounds). For these reasons, this approach will significantly reduce the subjective nature of classifying substances as either synthetic or nonsynthetic.

Graphic: http://www.accessexcellence.org/RC/VL/GG/cov_IonicBs.html
Access Excellence @ the National Health Museum

Comment: OTA's Technical Taskforce. This taskforce resubmits a decision tree on how to determine if something has undergone a chemical reaction. We recommend using this tool or something similar to assist in the decision making process.

5) "Substance":

Includes compounds and elements. Any synthetic substance for use in crops and livestock, and any non-organic substance for use in processing with a distinct identity (separate Chemical Abstract Society number, INS number, or FDA or other agency standard of identity) must be separately listed in the National List for use in organic production.

6) "Substances created by naturally-occurring biological processes" shall be understood to mean:

Chemical changes that occur in living cells or due to the action of products of living organisms, such as enzymes are not considered synthetic. For example, lactic acid is a non-synthetic substance that is the result of lactose (milk sugar) being fermented by the bacterium *Lactobacillus*.

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7) Non-synthetic (natural):

A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, non-synthetic is used as a synonym for natural as the term is used in the Act. [NOP.]

Comment: This taskforce recommends the following definition of “Non-synthetic”
In order to provide further clarification between synthetic and non-synthetic processes, we recommend the following revision to the NOP 205.2 Terms defined:

Nonsynthetic (natural): A substance that is naturally occurring in plants, animals, minerals, water or air or a substance that has been created by naturally occurring biological processes or food processing techniques/actions defined in the Act (“processing”). Nonsynthetic substances have not undergone changes to covalent bonds during manufacture except in the case of naturally occurring biological processes or accepted food processing techniques.

Conclusion

The proposed NOSB clarification of definitions regarding chemical reaction is useful for determining what substances are synthetic, and should be the basis for determination of synthetic status. Further attention to the definition of “extraction” and “substance” will also facilitate the determination. When reviewing substances, the NOSB must review the steps of production and determine if a chemical change occurred in manufacture of the substance. This may include whether the substance was extracted from a natural source in an acceptable manner.

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